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REMARKS/ARGUMENTS

Claims 2-13, 18-31, 33-43, and 45-54 remain in this application. Claims 1, 14-17, 32 and 44 were canceled. Claims 2-7, 10, 13, 18, 20-29, 31, 33, 35, 37, and 39-42 have been amended. Claims 51-54 were added above. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with marking to show changes made."**

The Office Action rejected claims 1-3, 5-6, 10, 16, 18, 20-27, 29, 31-33, 37, and 39-42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because of the use of parenthesis for the range of the UV radiation "(240-280 nm)", and to identify *Bacillus Stearothermophilus* "(ATCC 7953)". The Office Action suggested that it would be clearer for example to use the following: in the range of 240 to 280 nm in the above mentioned claims. Although this objection is traversed, the claims were amended above to eliminate the use of parenthesis. Therefore, it is respectfully requested that the 35 U.S.C. §112 rejection of the claims be withdrawn.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Matner, Shalaby, Dunn, and Heyl. The Office Action states:

"With respect to claims 1-19, Clark et al teaches a process and an apparatus for sterilizing a medical device (col. 1, lines 7-20) comprising the following concepts: subjecting a medical device (col. 1, lines 13-15) to UV radiation (col. 3, lines 60-62) in the range of 240-280 NM (col. 3, line 3) using energy value at least 3.9 mj/cm² (col. 8, lines 10-12). In addition; Clark et al teaches a sterility assurance level of at 10⁻⁶ (abstract, line 21). Furthermore; all the energy values in the claims fall within the teaching of Clark et al energy value range (col. 8, lines 10-12) which contains a specific low range value and a specific high range value. Clark et al goes on to further teach of specific energy values within this range (col. 8, lines 11-12). Moreover; Clark et al discloses the following concepts; the application of UV radiation to spores (col. 9, lines 50-53); the usage of at least one pulsed radiation source (col. 6, line 26 and col. 3, lines 51-56; various time ranges for applying the radiation which all the values in the claim falls into (col. 8, lines 12-19); more than 1 radiation source (col. 6, line 26); radiation sources pulse substantially simultaneously (col. 10, lines 35-37, since the reference establishes multiple flash lamps using time ranges which encompass all the time values of the claims); flash lamps comprises a reflector

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and a lamp (figure 1, 22) wherein the fluence of each is at the focal plane of reflector (figure 1, 22:20); pulsed radiation source in most three pulses (col. 9, lines 62-67 and col. 10, lines 33-37); wherein the medical device is in a container (col. 4, lines 55-57); container does have a transmissivity to UV radiation but no specific value was suggested (col. 4, lines 30-32); medical device is a contact lens (col. 4, lines 55-57); contact lens blocks at least 50% of the UV radiation (col. 4, lines 16-17, since the contact lens transmits more than about 1% which is equivalent to blocking UV radiation to at least 50%); and container comprises an aqueous solution (col. 8, line 4).

With respect to claims 1-19, Clark et al does not teach the following concepts: D values specific for *Bacillus Stearothermophilus* ATCC 7953; radiation is produced by a laser; determining the D value of *Bacillus Stearothermophilus* ATCC 7953 by mathematical relationship; and a specific transmissivity value for the container. However; Clark et al does provide examples of applying UV radiation to various types of spores (examples 1 and 2 wherein the D values of the spores is inherently represented by achieving a sterility of assurance level of at least 10^{-6}).

With respect to claims 20-41, Clark et al teaches a process and an apparatus for sterilizing a medical device (col. 1, lines 7-20) comprising the following concepts: modifying radiation from a radiation source to eliminate wavelengths which would damage medical device (col. 3, line 36 and line 38); medical device is in a hermetically sealed container (col. 8, lines 37-39); container comprises a non-preserved aqueous solution (col. 1, lines 10-13); container is transmissive to radiation in substantially all directions (col. 6, lines 45-55); the use of packages or containers is disclosed made of thermoplastics (col. 3, line 48 and col. 1, lines 29-30); at least one flash lamp containing a rare gas as a luminous component (col. 10, lines 20-25); an apparatus is light-tight (col. 8, lines 38-39); and forming a contact lens (col. 5, lines 43-61).

With respect to claims 20-41, Clark et al does not teach the following concepts: D values specific for *Bacillus Stearothermophilus* ATCC 7953; radiation is produced by a laser; determining the D value of *Bacillus Stearothermophilus* ATCC 7953 by a mathematical relationship; a specific transmissivity value for the container; and container comprises a lid and a bowl.

With respect to claims 42-50, Clark et al teaches a process and an apparatus for sterilizing a medical device (col. 1, lines 7-20) comprising the following concepts: at least one reflector directs radiation from each radiation source to a treatment area (figure 1, 18-22); treatment area is located at the focal plane of reflector (figure 8, 18:22 and the unlabeled rays); reflectors have enhanced reflection (col. 6, lines 42-44); and the reflector minimizes the non-ultraviolet radiation reaching the medical device (col. 6, lines 45-48). In addition; Clark et al teaches of a capacitance and a potential (col. 10, lines 1-8), however; Clark et al does not provide specific values for capacitance and for potential. Since the claims are trying to exactly accomplish what Clark et al teaches then it is inherent in the apparatus of Clark et al to encompass the same values for capacitance and a potential.

With respect to claims 42-50, Clark et al does not teach the following concepts: D values specific for *Bacillus Sstearothermophilus* ATCC 7953;

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radiation is produced by a laser; determining the D value of *Bacillus Stearothermophilus* ATCC 7953 by a mathematical relationship; a specific transmissivity value for the container; container comprises a lid and a bowl; specific range values for capacitance and for potential; and radiation sources are wired in series.

With respect to claims 1, and 15-16, Matner et al teaches of a method for determining the efficacy of sterilization cycle (col.1, lines 7-8) wherein it is known to use *Bacillus Stearothermophilus* ATCC 7935 to verify how efficient a sterilization cycle is (col. 2, lines 35-39).

Matner et al does not teach the following: D values specific for *Bacillus Stearothermophilus* ATCC 7953; forming contact lens; radiation is produced by a laser; determining the D value of *Bacillus Stearothermophilus* ATCC 7953 by a mathematical relationship; a specific transmissivity value for the container; container comprises a lid and a bowl; specific range values for capacitance and for potential; and radiation sources are wired in series.

With respect to claims 1, and 15-16, Shalaby et al teaches of methods of sterilization comprising, col. 2, lines 20-22; radiation source, col. 2, lines 20-48; wherein the concept of D-value is and its importance to sterility assurance level is explained, col. 3, lines 28-65; also the D-values of *Bacillus Stearothermophilus* are shown, columns 6-11 (examples 1-6). Furthermore; Shalaby teaches of known mathematical relationship between transmissivity, and D-values, col. 3, lines 46-57.

Shalaby et al does not teach the following: radiation is produced by a laser; a specific transmissivity value for the container; container comprises a lid and a bowl; specific range values for capacitance and for potential; and radiation sources are wired in series.

With respect to claims 13, 16, 31-33, 44-45, and 47, Dunn et al teaches of a method for sterilizing packaging of medical devices (col. 1, lines 17-21) wherein a laser is used (col. 2, lines 17-22); a container with at least 50% transmissivity to UV light is used (col. 6, lines 15-20); and specific range values for capacitance and for potential (col. 22, lines 23-25); and radiation sources are wired in series (figure 3, 358).

Dunn et al does not teach of container comprising a lid and a bowl.

With respect to claim 33, Heyl et al teaches of a method for sterilizing and disinfecting, col. 1, lines 11-16, wherein the container comprises a lid and a bowl, col. 9, lines 35-37.

Thus, it would have been obvious and one having ordinary skill in the art would have been motivated to combine the teaching of Clark et al for a system and a method of sterilizing a medical device by applying UV radiation to spores with another art-known in the determining the efficacy of sterilization cycles by specifically using *Bacillus Stearothermophilus* (ATCC 7935) bacterial spore for the known and expected results that the bacterial spore is recognized as the most resistant form of bacterial life and further all test for determining sterilization efficacy use it."

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Applicants traverse all the rejections above for all the reasons in the earlier Amendment filed April 19, 2001; however, in an effort to move this application to allowance, Applicants amended the claims herein. Applicants may decide to pursue the broader claims at a later time in a divisional application.

The broadest process claim provides for a method of sterilizing a contact lens within a container comprising the step of subjecting said contact lens to ultraviolet radiation in the range of 240 to 280 nm, wherein said contact lens is in a hermetically sealed container, and further wherein said container is transmissive to at least 50 % of said radiation in the range of 240 to 280 nm in substantially all directions. Clark teaches a contact lens container in which the lidstock comprises foil (col. 7, line 67). Foil is not transmissive to uv radiation. Clark states that the pulses of light are directed at the top of the polyolefin panel 54 and at the sides of the blister (col. 8, lines 6-8), and as a result, the microorganisms at the interior of the blister are deactivated (col. 8, lines 20-22). Additionally, Clark shows the radiation directed at the blister in Figures 4 and 6. Clark nowhere teaches nor suggests that the process of sterilizing a contact lens in a container should be modified so that the contact lens container is transmissive to at least 50 % of said radiation in the range of 240 to 280 nm in substantially all directions, as Applicants have claimed. Additionally, Clark provides no motivation to modify its process, because Clark states that the method disclosed therein deactivates the microorganisms. Clark and all the other cited references fail to teach or suggest modifying Clark's process of sterilization to use a container that is transmissive to at least 50 % of said radiation in the range of 240 to 280 nm in substantially all directions. Therefore, Applicants respectfully request the withdrawal of the rejection and the allowance of the process claims claims 2-13, 18-31, 33-41, and 51-54.

Regarding the apparatus claims, claim 42 claims an apparatus for delivering UV radiation to a medical device for sterilization comprising: at least one radiation source and a reflector for each said radiation source wherein at least one said reflector directs radiation from each said radiation source to a treatment area, such that at least 3 J/cm^2 broad spectrum radiation of which at least 50 mJ/cm^2 of said radiation is UV radiation in the range of 240 to 280 nm reaches said treatment area, said treatment area is located at the focal plane of said reflector, and further said treatment area is where said medical device is placed to receive the radiation wherein said apparatus further comprises a power supply which has a capacitance of 80 to 160 microFarad.

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No where does Clark or any other reference teach or suggest the particular apparatus that Applicants claim. No reference cited by the Office Action teaches or suggests the capacitance values that Applicants have specified.

For all the reasons herein and for the reasons stated in the Amendment filed April 19, 2001, that is incorporated herein by reference, especially regarding the rejections of the dependent claims, Applicants respectfully request that the rejections of the claims be withdrawn and that this application consisting of claims 2-13, 18-31, 33-43 and 45-54 be allowed to issue as a patent.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1, 14-17, 32 and 44 were canceled.

Claims 2-7, 10, 13, 18, 20-29, 31, 33, 35, 37, 39-42 were amended as follows:

2. (Amended once) The process of claim 52 [1] wherein to provide a sterility assurance level of 10^{-6} , said spore is exposed to at least 41 mJ/cm² of said UV radiation in the range of [(240 to 280 nm)] during said subjecting step.
3. (Amended once) The process of claim 52 [1] wherein to provide a sterility assurance level of 10^{-9} , said spore is exposed to at least 52 mJ/cm² of said UV radiation in the range of [(240 to 280 nm)] during said subjecting step.
4. (Amended once) The process of claim 52 [1] wherein said radiation is delivered to said spore by at least one pulsed radiation source.
5. (Amended once) The process of claim 4 wherein each pulse delivers at least 20 mJ/cm² UV radiation in the range of [(240 to 280 nm)] to said spore.
6. (Amended once) The process of claim 52 [1] wherein at least 18 mJ/cm² UV radiation from [(240 to 280 nm)] is delivered in less than 1 millisecond to said spore.
7. (Amended once) The process of claim 51 [1], wherein said radiation is delivered by more than 1 radiation source.
10. (Amended once) The process of claim 9, wherein said flash lamps each comprise a reflector and a lamp wherein the fluence of each of said flash lamps at the focal plane of said reflector is at least 45 mJ/cm² UV radiation in the range of [(240 to 280 nm)].
13. (Amended once) The process of claim 51, wherein said radiation is produced by a laser.

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18. (Amended once) The process of claim 51 [17], wherein said contact lens blocks at least 50 percent of the UV radiation in the range of [(240 to 280 nm)].

20. (Amended once) The [A] process of claim 51 [sterilizing a medical device comprising:
subjecting said medical device to ultraviolet radiation] wherein the minimum total energy density of said ultraviolet radiation in the range of [(240 to 280 nm)] to microorganisms on said [medical device] contact lens is at least 18 mJ/cm².

21. (Amended once) The process of claim 20, wherein the minimum total energy density of said ultraviolet radiation in the range of [(240 to 280 nm)] to said microorganisms is at least 30 mJ/cm².

22. (Amended once) The process of claim 20, wherein the minimum total energy density of said ultraviolet radiation in the range of [(240 to 280 nm)] to said microorganisms is at least 36 mJ/cm².

23. (Amended once) The process of claim 20, wherein said minimum total energy density of said ultraviolet radiation in the range of [(240 to 280 nm)] is delivered to said microorganisms in less than 20 seconds.

24. (Amended once) The process of claim 21, wherein said minimum total energy density of said ultraviolet radiation in the range of [(240 to 280 nm)] is delivered to said microorganisms in less than 1 second.

25. (Amended once) The process of claim 21, wherein said minimum total energy density of said ultraviolet radiation in the range of [(240 to 280 nm)] is delivered to said microorganisms in less than 1 millisecond.

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26. (Amended once) The process of claim 22, wherein said minimum total energy density of said ultraviolet radiation in the range of [(240 to 280 nm)] is delivered to said microorganisms in less than 1 millisecond.
27. (Amended once) The process of claim 20, wherein said radiation is provided by a pulsed radiation source which provides at least 20 mJ/cm² ultraviolet radiation in the range of [(240 to 280 nm)] per pulse to said microorganisms.
28. (Amended once) The process of claim 20, wherein prior to said subjecting step is the step of modifying radiation from a radiation source to eliminate wavelengths which would damage said [medical device] contact lens.
29. (Amended once) The process of claim 21, [wherein said medical device is in a hermetically sealed container and] wherein said minimum total energy density of said ultraviolet radiation in the range of [(240 to 280 nm)] which reaches said microorganisms, further reaches said contents of said container whereby the entire contents of said container and said medical device are sterilized.
31. (Amended once) The process of claim 30 wherein said container is transmissive to at least 50 % of said ultraviolet radiation in the range of [(240 to 280 nm)].
33. (Amended once) The process of claim 51 [32] wherein said container comprises a lid and a bowl, wherein said lid and said bowl comprise thermoplastics and said lid and said bowl are transmissive to at least 50% of said radiation in the range of [(240 to 280 nm)] in substantially all directions.
35. (Amended once) The process of claim 34 [wherein said medical device is a contact lens, and] wherein said subjecting step follows the steps of:
- (a) forming a contact lens;
 - (b) placing said contact lens in a container; and
 - (c) moving said container into an apparatus comprising a radiation source;
- and wherein said apparatus is light-tight during said subjecting step.

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37. (Amended once) The process of claim 35 wherein said medical device comprises a contact lens comprising UV-blocker which blocks greater than 50 % of the radiation in the range of 240 to 280 nm [between 240-280 nm].

39. (Amended once) The process of claim 37 wherein, the amount of said ultraviolet radiation in the range of [(240 to 280 nm)] delivered to said contact lens is between 18 mJ/cm² and 150 mJ/cm².

40. (Amended once) The process of claim 39 wherein said flash lamps deliver at least 80 mJ/cm² total UV radiation in the range of [(240 to 280 nm)] per flash to said container.

41. (Amended once) The process of claim 39 wherein said flash lamps deliver at least 100 mJ/cm² total UV radiation in the range of [(240 to 280 nm)] per flash to said container.

42. (Amended once) An apparatus for delivering UV radiation to a medical device for sterilization comprising:

at least one radiation source and a reflector for each said radiation source wherein at least one said reflector directs radiation from each said radiation source to a treatment area, such that at least 3 J/cm² broad spectrum radiation of which at least 50 mJ/cm² of said radiation is UV radiation in the range of [(240 to 280 nm)] reaches said treatment area, said treatment area is located at the focal plane of said reflector, and further said treatment area is where said medical device is placed to receive the radiation, and said apparatus further comprises a power supply which has a capacitance of 80 to 160 microFarad.

Claims 51-54 were added as follows:

—51. A process of sterilizing a contact lens within a container comprising the step of:
subjecting said contact lens to ultraviolet radiation in the range of 240 to 280 nm, wherein said contact lens is in a hermetically sealed container, and further wherein said

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container is transmissive to at least 50 % of said radiation in the range of 240 to 280 nm in substantially all directions.

52. The process of claim 51 wherein said subjecting step further provides:
subjecting said medical device to ultraviolet radiation whereby the D_{value} of Bacillus stearothermophilus, ATCC 7953, is at least 3.9 mJ/cm^2 ultraviolet radiation in the range of 240 to 280 nm to the spore.

53. The process of claim 52, wherein said D_{value} of Bacillus stearothermophilus, ATCC 7953, can be determined for a container by dividing 3.9 mJ/cm^2 by the transmissivity of said container exposed to said radiation source.

54. The process of claim 53, wherein the D_{value} of Bacillus stearothermophilus is at least 7.8 mJ/cm^2 ultraviolet radiation in the range of 240 to 280 nm to the outside of said container, said container has a 50 % transmissivity to said ultraviolet radiation in the range of 240 to 280 nm.--